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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,128	05/06/2005	Mi-Chung Suh	ZEN-0002	2798
34610	7590	06/12/2007		
KED & ASSOCIATES, LLP P.O. Box 221200 Chantilly, VA 20153-1200			EXAMINER BAGGOT, BRENDAN O	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,128	SUH ET AL.	
	Examiner	Art Unit	
	Brendan O. Baggot	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 drawn to SEQ ID NO: 3 is/are pending in the application.
- 4a) Of the above claim(s) 3,7 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction / Election

1. The Office acknowledges the receipt of Applicant's restriction election, filed 4/23/07. Applicant elects Group I, claims 1-2, 4-6 drawn to a promoter, SEQ ID NO: 3, with traverse stating the nonelected intron should be examined and that an intron and a promoter are somehow both species of the same genus. Applicant's traversal is unpersuasive for the following reasons: While a search of the prior art for one group may overlap with that of another group, they are not co-extensive of each other and thus would represent undue burden on Office resources. Applicant's species argument is without merit.

2. Claims 3, 7, and 12 and sequences other than SEQ ID NO: 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/23/07.

3. This restriction is made FINAL.

Notice of Non-Compliant Amendment

(c) Claims. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by

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underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn— currently amended."

37 CFR § 1.121

4. Applicant's amendment to the claims 10 & 11 failed to comply with rule 1.121(c)(2). Any further failure to comply with the rule will be found non-responsive.

Sequence Listing

5. Applicant's computer readable format sequence listing has been entered.

Drawings

6. The drawings are acceptable for examination.

Claim Rejections - 35 U.S.C. §101, lack of utility

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to unisolated nucleotide sequences, which are indistinguishable from naturally occurring nucleotides found in whole plants. Amendment of the claims 1 to replace "A" with - - - An isolated - - - would overcome this rejection. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1874); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed*

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Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 U.S.C. §112, first paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 4-6, 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 3 expression in *Arabidopsis*, does not reasonably provide enablement for in any plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The *Wands* court set forth the enablement balancing test:

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.'"

M.P.E.P. § 2164.01(a); *See also Ex Parte Forman* 230 USPQ 546, 547 (BdPatApplnt 1986); *See also Enzo Biochem, Inc., v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999).

Applicant's claims are broadly drawn to any seed-specific promoter which is capable of initiating expression in any species and which contains 482 to 608 of SEQ ID NO: 3 or SEQ ID NO: 3.

Applicants teach a 660 base pair SEQ ID NO: 3 (sequence listing) and fragments thereof with promoter activity in *Arabidopsis thaliana* and sesame, *Arabidopsis thaliana* seed specific expression of SEQ ID NO: 3 plus 0 to 141 of SEQ ID NO: 1 (Example 4, page 14, lines 12-13; Figure 12a, clones SiW6F1, -660 to 141; SiW6F2, -547 to 141; SiW6F3, -346 to 141; SiW6F4, -179 to 141; SiW6F5, -52 to 141).

Applicants do not teach any seed-specific promoter which is capable of initiating expression *in any species* and which contains 482 to 608 of SEQ ID NO: 3 or is SEQ ID NO: 3.

The Breadth Of The Claims

The claims are broadly drawn to and encompass all plant species of any kind. The broad language expressly includes plants which do not contain the compounds responsible for up and down regulation of SEQ ID NO: 3 and its promoter fragments.

The Unpredictability of the Art and the State of the Prior Art

The state-of-the-art is such that one of skill in the art cannot predict which plants will have conserved plant gene expression profiles. There is abundant prior art to suggest that achieving heterologous expression of promoters and promoter elements is

difficult, unpredictable and unsuccessful. Reviews by Oommenn and by Hauschild detail a variety of problems seen in heterologous expression of promoters.

Using a promoter isolated from one species would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant. Oommenn et al (1994) *The Plant Cell* 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavones reductase promoter expressed in vegetative tissues and in reproductive organs, whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants. (See abstract). Cf. Facchini et al, (1998) *Plant Physiol.* 118:69-81.

Hauschild et al (1998) *Plant Molecular Biology*, vol. 36, pp. 473-478) teaches that heterologous expression of promoters is highly unpredictable and that there was an unexpectedly high species specificity of poppy alkaloid pathway regulatory regions. Hauschild found that the berberine bridge enzyme (BBE1) promoter, when operably linked to GUS, was active in only 2 out 28 plant species tested and was only able to determine this after undue trial and error experimentation. (See Table 2, Abstract, page 477, right column, first full paragraph). Positive control 35S – GUS constructs showed notably different results. Id. Thus, heterologous expression of promoters such as SEQ ID NO: 3 – the SiFAD2 promoter – is highly unpredictable and promoters are difficult to identify, and identification is unpredictable because even if one had the sequence of the entire sesame genome, including all the promoters, when put into a model system, the skilled artisan would not see any expression in many plants and thus would not discover

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that the SiFAD2 operon or DNA region of interest contained or was a promoter. The skilled artisan would have to depend on luck that he uses the right model system.

The specification did not provide any guidance on how to determine which plants would have conserved expression patterns.

In the instant case, along with the absence of working examples, the relatively small amount of guidance in the specification, the unpredictability in the art and the large amount of experimentation would be necessary to achieve function balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC §112, first paragraph, lack of enablement/deposit

Claims 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 6 and 9 require a particular cloning vector strain, namely pBinSiFAD2-GUS. The specification does not provide any guidance regarding the composition of said strain, the location of the deposit of the cells, or any guidance regarding any particular culturing, plating, or employing methods. Accordingly, one skilled in the art would not know how to make and/or use said plasmids.

The invention appears to employ novel vectors. Since the vector is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the vector is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the bacteria containing the vector. The specification does not disclose a repeatable process to obtain the bacteria containing the vector, and it is not apparent if the bacteria containing the vector is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

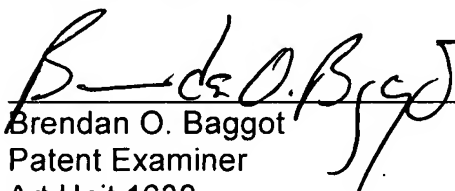
Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

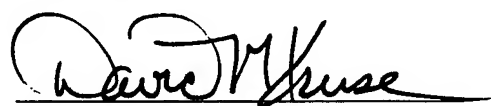
8. All Claims are rejected. SEQ ID NO: 3 is deemed free of the prior art given the failure of the prior art to teach or reasonably suggest an isolated nucleic acid molecule encoding SEQ ID NO: 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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